

Combined caBIG® Tools as a Solution for Translational Research

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University of Arkansas for Medical Sciences
Winthrop P. Rockefeller Cancer Institute

caBIG® Tools: Solutions for Translational Research

- Our institution
- Overall vision
- What we have implemented
- Techniques used to move forward
- Specific research initiatives

Who We Are

The University of Arkansas for Medical Sciences (UAMS)
is part of the University of Arkansas system

- The flagship campus (Univ. of Arkansas) is located in the Northwest corner of the state
- UAMS is located in Little Rock which is in the center of the state and also home of the state capitol.
- UAMS is the sole medical school for the Arkansas
- The UAMS campus is a health sciences campus with six Colleges: Medicine, Pharmacy, Nursing, Public Health, Health Related Professions, and Graduate Studies. Interwoven into the Colleges are six Institutes: Cancer, Aging, Psychiatry, Myeloma, Eye, and Spine & Neurosciences.

Who We Are

The University of Arkansas for Medical Sciences (UAMS)

- UAMS recently established a satellite medical school, and also operates 8 Area Health Education Centers (AHECs) and 6 satellite Aging Clinics dispersed throughout the state.
- On 07/14/2009 UAMS was awarded a nearly \$20 million NIH CTSA grant, based upon its strength in telemedicine and community programs, amongst other initiatives.

Who We Are

- The Winthrop P. Rockefeller Cancer Institute at UAMS
 - The Rockefeller Cancer Institute opened in 1989 as the Arkansas Cancer Research Center. In 2004 it was proclaimed as the official cancer institute for the state of Arkansas by then Governor Mike Huckabee.
 - The Cancer Institute's first tower, named in honor of Willard & Pat Walker, was constructed in 2 stages and was fully complete in 1994. It included both outpatient clinical space as well as clinical and bench research space.
 - By 2004, it was decided that an expansion tower would be needed.

Who We Are

- The Winthrop P. Rockefeller Cancer Institute at UAMS
 - In 2007, ground was broken for building a 12-story 350,000 sq ft expansion tower, which is twice the size of the Walker Tower. The new tower adjoins the Walker Tower such that the two towers will work as one. The first phase was completed in the summer of 2010.
 - Also in 2007, the Cancer Institute adopted the name Winthrop P. Rockefeller. Winthrop Rockefeller was one of John D. Rockefeller, Jr.'s five sons and served as Arkansas Governor from 1967-1971 before succumbing to pancreatic cancer. Winthrop P. Rockefeller was Winthrop's only child and served as Lieutenant Governor of Arkansas for 10 years before dying of a blood cancer in 2006.

Who We Are

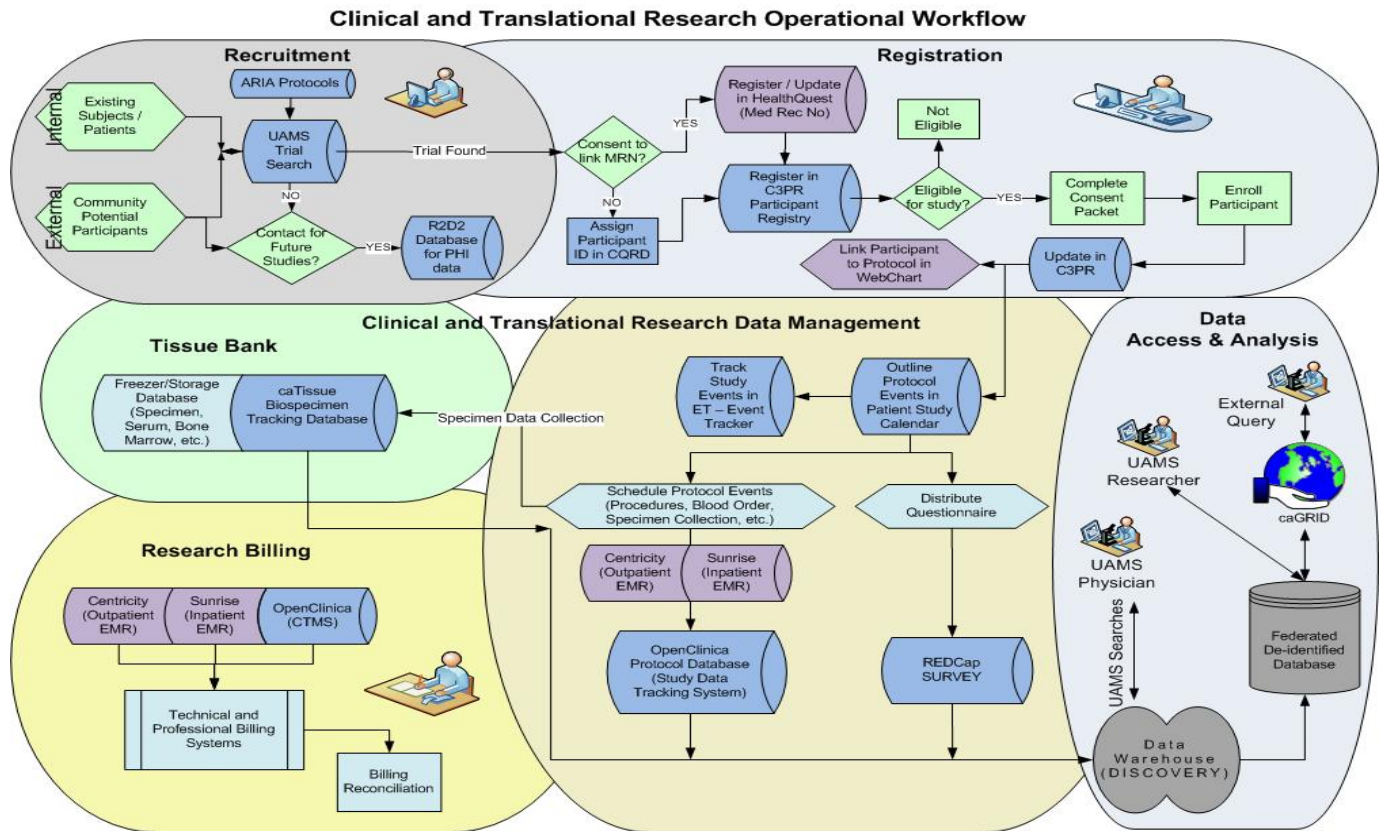


- Some of the strengths of the Rockefeller Cancer Institute at UAMS include: molecular epidemiology, cancer control, disparities, bone metastases, multiple myeloma, immunotherapy, behavioral oncology, radiation injury and radiation biology, and laser detection of circulating tumor cells.

Who We Are



Vision



Vision

- System that would facilitate
 - Recruitment
 - Registration
 - Trial management (therapeutic and other)
 - Regulatory
 - Data
 - Adverse events
 - Tissue
 - Biologic information
 - Billing

Vision

- Integrated
 - Allow the maximal use of data
 - Connect clinical information to biologic data
- Expandable
 - Unite Area Health Education Centers
 - Community research
- Flexible
 - Epidemiologic, therapeutic, translational
- Affordable for our rural partners

caBIG®Tools:

Solutions for Translational Research

- At the beginning
 - No central support
 - Each researcher built their own
 - Problems escalated
- Back-up
- Security
- Began with ARIA for IRB support

Clinical Trials Management Dashboard

- Crimson
- ARIA
- caBIG® Cancer Central Clinical Participant Registry (C3PR)
- caBIG® Patient Study Calendar
- OpenClinica
- Trial Search
- Event Tracker

UAMS Single Sign-On

- Single sign-on
- Future enhancement to provide secure access by outside users
- Domain Username and Password

UAMS Dashboard

UAMS

University of Arkansas
Medical System

Practical Clinical Trials Management

Welcome Cheryl Lane!

DashboardARIACRIMSONC3PREStudy CalendarOpenClinicaETTrialSearch

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Regulatory Applications

- Crimson: Budget building tool
- Aria: IRB management
- Event Tracker: Tracks the life of the protocol and sends reminders to staff

UAMS ARIA, CRIMSON, Contracts



ARIA
AUTOMATED RESEARCH INFORMATION ADMINISTRATOR

The overall objective of ARIA is to provide an integrated environment for the exchange of information from ORSP, IRB, Office for Clinical Trials, Animals, Biosafety, and Laboratory for UAMS campus-wide research. ARIA is designed to be a major component of a comprehensive solution for the information technology needs of administration, researchers, and institutions while maintaining an emphasis on compliance with regulatory requirements. Through implementation of ARIA, researchers will be provided a supporting infrastructure to continue their mission to engage in activities that improve the health and well-being of people and animals.

ARIA is supported in part by the National Center for Research Resources of the National Institutes of Health.

ARIA
AUTOMATED RESEARCH INFORMATION ADMINISTRATOR

CONTRACTS | REPORTS | RESEARCH | ARIA PROTOCOLS

Search

Jump to IRB #

View Filter	Study Category	Principal Investigator	Approval Status	Status
IRB#	Study Category	Principal Investigator	Approval Status	Status
IRB# 111326	ADAP Prevention Services Program Grant Evaluation	Investigator Initiated	Study Entry in Progress	Saved
IRB# 111307		Investigator Initiated	Study Entry in Progress	Saved
IRB# 111320		Investigator Initiated	Study Entry in Progress	Saved
IRB# 111345	The Expression of PTEN Protein and mTOR in Wavelength Cells of Ovaries	Investigator Initiated	Study Entry in Progress	Saved
IRB# 111225	Single Patient Compassionate Use of Carfilzomib in T-cell ALL	Investigator Initiated	Submission Incomplete	Saved
IRB# 111124	Single Patient Compassionate Use of Carfilzomib in T-cell ALL	Investigator Initiated	Submission Incomplete	Saved
IRB# 111223	Single Patient Compassionate Use of Carfilzomib in T-cell ALL	Investigator Initiated	Submission Incomplete	Saved
IRB# 111221		Investigator Initiated	Study Entry in Progress	Saved
IRB# 111228	Ar Open Label, Multicenter Phase II Trial of AB-007 VS Docetaxel in ...	Industry Sponsored	Study Entry in Progress	Saved

Page 1 of 20

ARIA
AUTOMATED RESEARCH INFORMATION ADMINISTRATOR

CONTRACTS | REPORTS | RESEARCH | ARIA PROTOCOLS

Work List

Search

View: All Status

Contract Number	IRB Number	Principal Investigator	Contract Type	Contract Entity	Approval Status	Date of Creation
C10477-2009	N/A	Maddox, Anne-Marie	Confidential Disclosure Agreement (CDA)	GlandSinteline	New Contract	07/17/2009
C10476-2009	N/A	Yaccoby, Shmuel	Material Transfer Agreement (MTA)	Amgen Pharmaceuticals, Inc.	New Contract	07/17/2009
C10475-2009	N/A	Yaccoby, Shmuel	Confidential Disclosure Agreement (CDA)	Amgen Pharmaceuticals, Inc.	New Contract	07/17/2009
C10474-2009	N/A	Topaloglu, Umit	Confidential Disclosure Agreement (CDA)	Elagira Software Technologies	In Contract Review	07/17/2009
C10473-2009	N/A	Maddox, Anne-Marie	Clinical Trial Agreement (CTA)	Phar Inc.; INC Research Inc.	In Contract Review	07/16/2009
C10472-2009	105792	Shihabuddin, Bashir	Other	Phar	In Contract Review	07/16/2009
C10471-2009	N/A	Palmer, Kristine	Confidential Disclosure Agreement (CDA)	Biogenomics Inc.; Omimetrics/CRO	In Legal Review	07/15/2009
C10467-2009	N/A	Stack, Brendan	Clinical Trial Agreement (CTA)	Esai Medical Research Inc.; IRD Development (CRO)	In Contract Review	07/15/2009

UAMS Event Tracker (ET)

UAMS | Clinical Trials Management Welcome Umit Topaloglu!

[Dashboard](#) | [ARIA](#) | [CRIMSON](#) | [C3PR](#) | [Study Calendar](#) | [OpenClinica](#) | **ET** | [TrialSearch](#)

ET EVENT TRACKER FOR REGULATORY SUBMISSIONS
UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

Search by for

IRB# 99075: "A Preliminary Study Utilizing a Flexible Endoscope for Pelvic Culdoscopy"

Dates | [Events](#) | [Disease Site / Subsite](#)

Dates

ARIA / CRIMSON

Original Submission 02/22/2008

CRIMSON Approval 02/21/2008

IRB Approval 06/10/2008

CRIMSON Submission 01/22/2008

Last Continuing Review 04/27/2009

Next Continuing Review 04/27/2010

CRDM Specific

Initial Committee Approvals

PRMC

Sent

Approved

Biosafety Committee

Sent

Approved

Radiation Safety Committee

Sent

Approved

Related Details

Initiation

Activation
(Open to enroll)

Temporary Closure

Closed to
Enrollment

Study Management Tools

- Trial Search
- caBIG® C3PR
- caBIG® Patient Study Calendar
- OpenClinica
- caBIG®caAERS
- Labviewer
- LimeSurvey

UAMS TrialSearch

UAMS

Clinical Trials Management

Welcome Gail Douglas!

DashboardARIACRIMSONC3PRStudy CalendarOpenClinicaET

TrialSearch

UAMSTrialSearch

Search for

Browse trials by [Disease](#) | [Investigator](#) | [Treatment](#) | [Sponsor](#) | [Cancer Specific](#)

Welcome douglasgailh (Admin) | [Logout](#)

Administer protocols

Choose a disease site / subsite

[Adolescent Health](#) (2 studies)

[Aging](#) (3 studies)

[Bacterial and Fungal Diseases](#) (1 studies)

[Bacterial and Fungal Diseases](#) >> [Blastomycosis](#) (1 studies)

[Behaviors and Mental Disorders](#) >> [Amphetamine-Related Disorders](#) (3 studies)

[Behaviors and Mental Disorders](#) >> [Cocaine-Related Disorders](#) (1 studies)

[Behaviors and Mental Disorders](#) >> [Marijuana Abuse](#) (1 studies)

[Behaviors and Mental Disorders](#) >> [Substance-Related Disorders](#) (3 studies)

[Biobehavioral Health](#) (9 studies)

[Bioterrorism](#) (1 studies)

[Blood and Lymph Conditions](#) >> [Anemia, Neonatal](#) (1 studies)

[Blood and Lymph Conditions](#) >> [Blood Coagulation Disorders, Inherited](#) (1 studies)

[Blood and Lymph Conditions](#) >> [Vascular Hemostatic Disorders](#) (1 studies)

[Cancers and other Neoplasms](#) >> [Adenocarcinoma](#) (1 studies)

[Cancers and other Neoplasms](#) >> [Bladder Neoplasms](#) (1 studies)

[Cancers and other Neoplasms](#) >> [Bone Neoplasms](#) (4 studies)

[Cancers and other Neoplasms](#) >> [Brain Neoplasms](#) (1 studies)

[Cancers and other Neoplasms](#) >> [Breast Neoplasms](#) (5 studies)

[Cancers and other Neoplasms](#) >> [Carcinoma](#) (2 studies)

[Cancers and other Neoplasms](#) >> [Carcinoma, Lobular](#) (1 studies)

[Cancers and other Neoplasms](#) >> [Carcinoma, Renal Cell](#) (1 studies)

[Cancers and other Neoplasms](#) >> [Carcinoma, Small Cell](#) (1 studies)

[Cancers and other Neoplasms](#) >> [Carcinoma, Squamous Cell](#) (1 studies)

[Cancers and other Neoplasms](#) >> [Gastrointestinal Neoplasms](#) (1 studies)

[Cancers and other Neoplasms](#) >> [Head and Neck Neoplasms](#) (2 studies)


[Cancers and other Neoplasms](#) >> [Lung Neoplasms](#) (1 studies)

[Cancers and other Neoplasms](#) >> [Lymphatic Vessel Tumors](#) (1 studies)

[Cancers and other Neoplasms](#) >> [Melanoma](#) (5 studies)

[Cancers and other Neoplasms](#) >> [Multiple Myeloma](#) (16 studies)

caBIG® Cancer Central Clinical Participant Registry



UAMS

Welcome Matt Baker | Admin

Dashboard
Close window

RegistrationStudiesPerson & OrganizationAdministrationAdvanced Search

Frequently Used Shortcuts

[Search Study](#)[Create Study](#)[Create Registration](#)[Manage Registration](#)

Notifications

[My Inbox](#)

You don't have any notifications.

C3PR Development Notes

[C3PR Wiki](#)[C3PR User Guide](#)[Check Deployment Status](#)

Build Number: C3PR v. 2.6.1

Incomplete Registrations - Most Recent


Subject name	Primary Identifier	Title	Registration status
thomas kieber-emmons	23674329	testcdm	Pending
jason smith	397042	UARK 2004-19, Randomized, Double-Blind Multicenter Phase II Study of Time to Progression on Fulvestrant in Combination with Ertotimb or Placebo in Hormone Receptor-Positive Metastatic Breast Cancer (MBC) Subjects who Progressed on First Line Hormonal Therapy	Pending

Pending Studies - Most Recent


Most Active Studies

Title	Primary Identifier	Coordinating center	Accrual w/in last week
UARK 2004-19, Randomized, Double-Blind Multicenter Phase II Study of Time to Progression on Fulvestrant in Combination with Ertotimb or Placebo in Hormone Receptor-Positive Metastatic Breast Cancer (MBC) Subjects who Progressed on First Line Hormonal Therapy	57485	UAMS - CRDM	1
testcdm	uamscdm	UAMS - CRDM	1
SWOG 0500, A Randomized Phase III Trial to Test the Strategy of Changing Therapy Versus Maintaining			

C3PR: Importing a Subject



C3PR
CANCER CENTRAL CLINICAL
PARTICIPANT REGISTRY



UAMS
UNIVERSITY OF ALABAMA
AT MONTGOMERY

Welcome Matt Baker | Admin

[Dashboard](#)
[Close window](#)

[Registration](#)[Studies](#)[Person & Organization](#)[Administration](#)[Advanced Search](#)

[Subject](#)[Investigator](#)[Research Staff](#)[Organization](#)

[Search Subject](#)[Create Subject](#)

Search

Instructions To search for a Subject, first select a Last Name, First Name or Identifier, enter the Search Criteria (e.g. Subject last name), and then click Search. Leave the Search Criteria field blank to search for all subjects.

Search by

Search criteria

UAMS Patient Search

Search by MRN

C3PR: Importing a Subject (search)

C3PR
CANCER CENTRAL CLINICAL PARTICIPANT REGISTRY

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Dashboard
Close window

Registration Studies Person & Organization Administration Advanced Search

Subject Investigator Research Staff Organization

Search Subject Create Subject

UAMS Patient Search

UAMS

Choose a patient to copy to C3PR, or search for another patient below.

MRN Search

MRN	Name	Sex	Birthday	Action
0012		Female	10/8/19	Already in C3PR
0008		Female	7/10/19	Copy to C3PR
0012		Female	7/2/19	Copy to C3PR
0012		Male	7/15/19	Copy to C3PR
0012		Female	9/4/19	Copy to C3PR

Search by MRN Search

C3PR: Subject is Imported

Subject Summary

Basic Details

First name [REDACTED]
Last name [REDACTED]
Middle name [REDACTED]
Maiden name [REDACTED]
Social security number [REDACTED]
Gender Female
Birth date 10/07/1967
Ethnicity Unknown
Race(s) Black or african american

Address

Street address [REDACTED]
City [REDACTED]
State [REDACTED]
Country [REDACTED]
Zip [REDACTED]

Contact Information

Email	Phone	Fax
[REDACTED]		

Identifiers

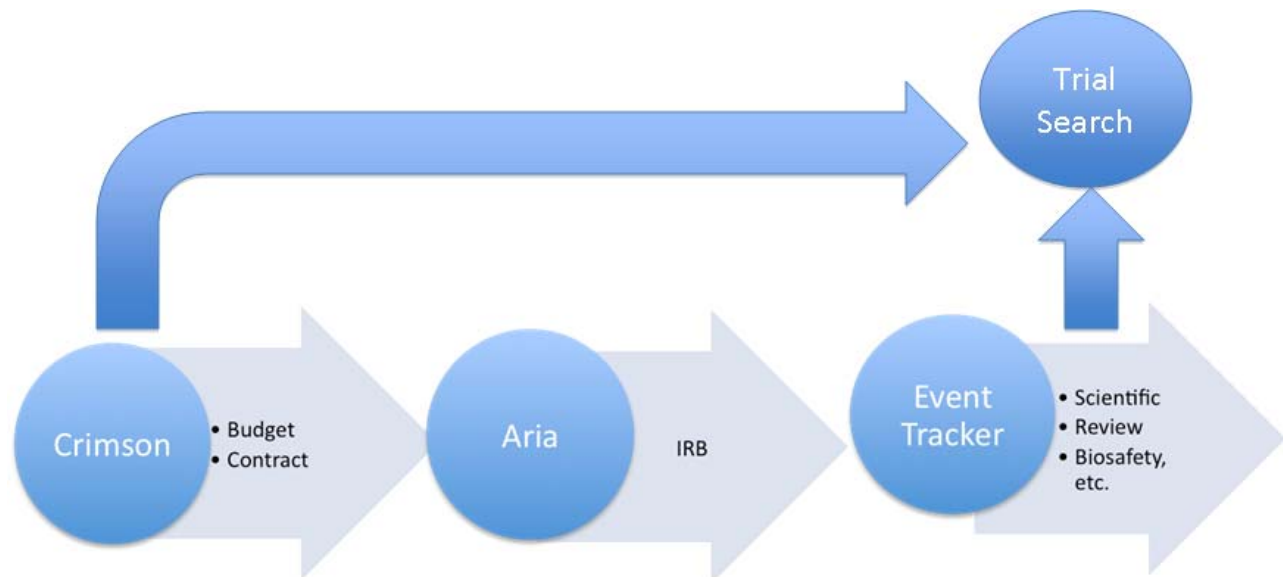
Organization Assigned Identifiers

Assigning authority	Identifier type	Identifier
UAMS	MRN	001 [REDACTED]

C3PR

- Currently 143 protocols loaded
- 1507 subjects registered
- Accomplished over 3 months
- 3 regulatory specialists
- 2 CRA's

Interaction of Tools



caBIG® Patient Study Calendar

UAMS | Clinical Trials Management

Welcome Gail Douglas!

DashboardARIACRIMSONC3PRStudy CalendarOpenClinicaETTrialSearch

psCalendarPSC HomeCalendarsActivitiesAdministrationReport

Tasks: Subject CoordinatorStudy CoordinatorSite CoordinatorStudy Admin

Dashboards / Subject coordinator

Welcome, douglasgailh

Past-due activities

Hans Douglas has [3 past-due activities](#). Earliest is from 03/04/2009

Current activities

Activities for the next days

Filter by activity type: ☒ Disease Measure ☒ Intervention ☒ Lab Test ☒ Procedure ☒ Other

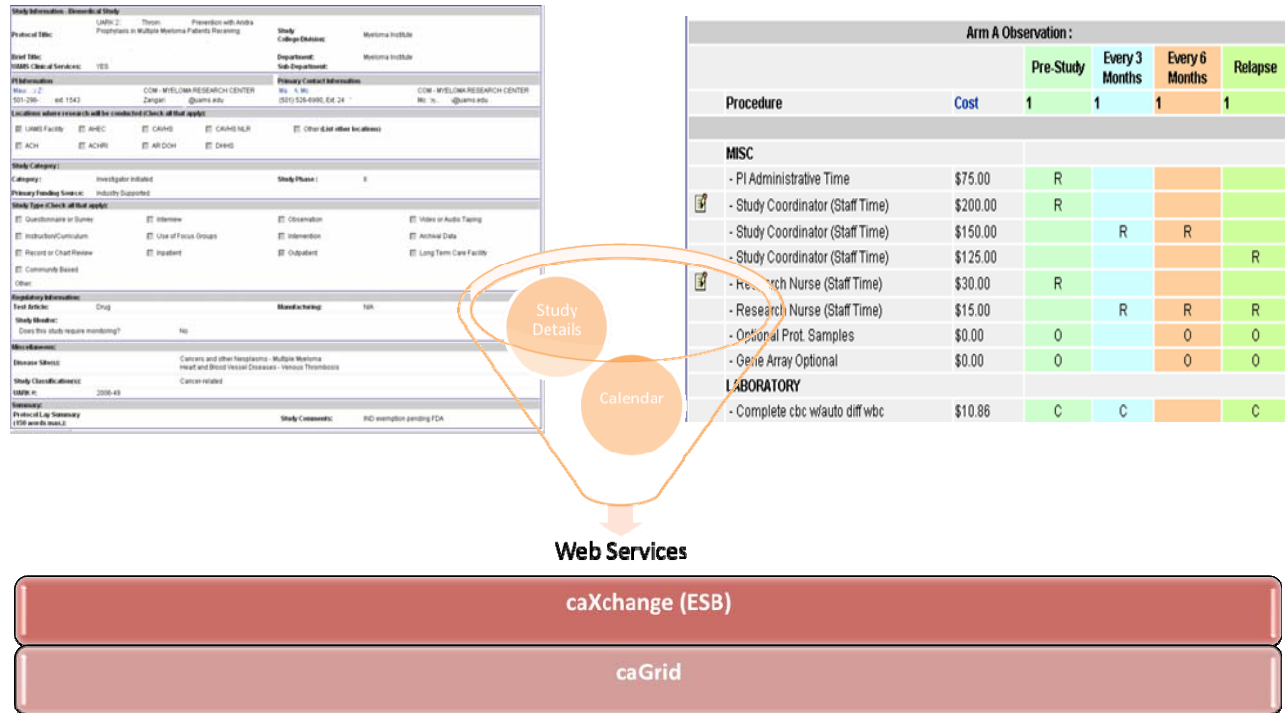
No scheduled or conditional events for the next 7 days in the selected categories.

Available studies

[Test_01-27_Victoria](#) +

Current Project

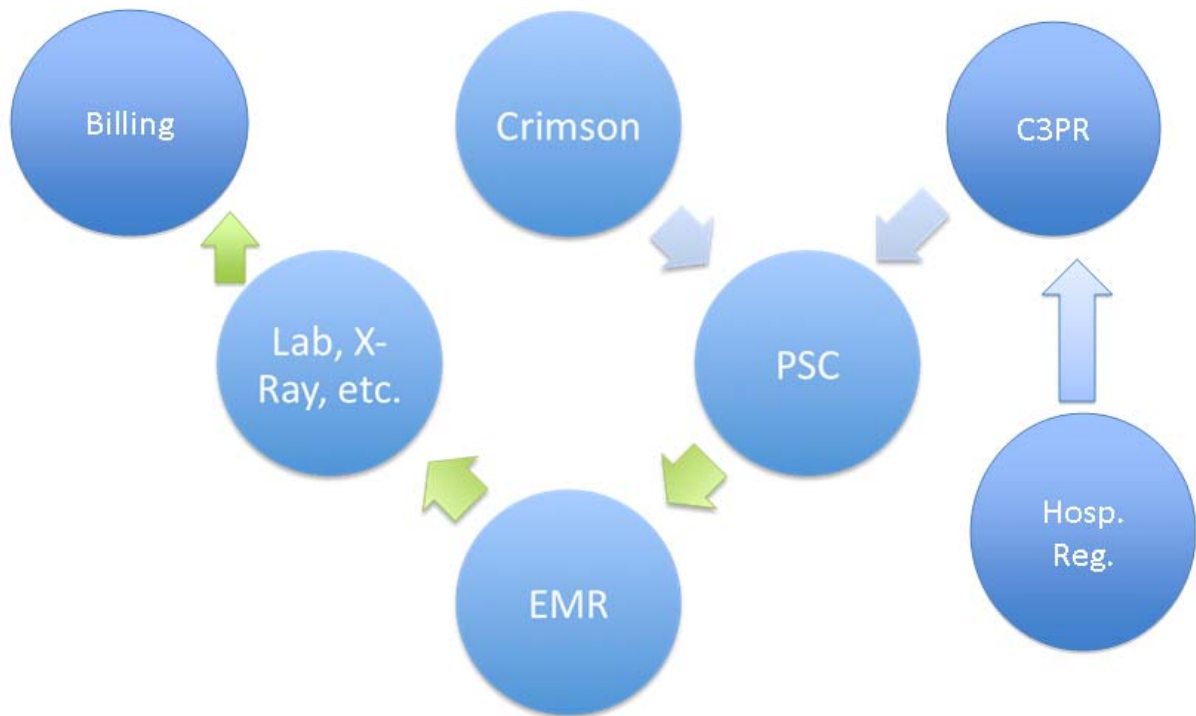
Interface UAMS CRIMSON Study/Budget to PSC



Crimson/PSC

- Protocol activities specified by CPT code in Crimson
- Not useful for clinical calendars
- “Translate” into Snomed
- Maintain tie to CPT code and charge type
- See calendar in EMR with Snomed designation
- Interface to orders and billing to allow ordering of studies with correct account number

Interaction of Tools



LabViewer (in progress)

LabViewer Clinical Trials Object Data System (CTODS)

Home Lab Activities Test

Tasks: Search lab activities

Lab Activities - Search Results

Add New LabResults

View this patient in caAERS

<input checked="" type="checkbox"/>	Patient Id	Date / Time	Lab Test	Text Result	Numeric Result	Unit Of Measure	Lower Limit	Upper Limit	Sent to CDMS	Sent to caAERS
<input type="checkbox"/>	00-00-00-0	4/29/05 10:28 PM	BUN		11.0	mg/dL	8.0	22.0	false	false
<input type="checkbox"/>	00-00-00-0	4/29/05 10:28 PM	BUN		11.0	mg/dL	8.0	22.0	false	false
<input type="checkbox"/>	00-00-00-0	4/29/05 10:28 PM	BUN		11.0	mg/dL	8.0	22.0	false	false
<input type="checkbox"/>	00-00-00-0	10/7/05 8:14 PM	BUN		20.1	mg/dL	11.0	1.0	false	false
<input type="checkbox"/>	00-00-00-0	10/6/05 8:14 PM	BUN	PLASMA		count	0.0	0.0	false	false

Cancel Load Labs to caAERS Load Labs to CDMS Save Labs to CSV

- Written a program which utilizes the lab loader and LabViewer persistence modules in LabViewer which allows a manual parsing and insertion of HL7 v3 files into CTODS

OpenClinica

UAMS | Clinical Trials Management Welcome Gail Douglas!

Dashboard ARIA CRIMSON C3PR Study Calendar **OpenClinica** ET TrialSearch

OpenClinica [Home](#) [Submit Data](#) [Extract Data](#) [Manage Study](#) [Business Admin](#) [Report Issue](#) | [Support](#)

User: douglasgail
Study: (99075) A Preliminary Study Utilizing a Flexible Endoscope for Pelvic Culdoscopy
Protocol ID: 99075
Role: Data Manager
[Change Study/Site](#) [Log Out](#)

Alerts & Messages
Welcome to OpenClinica, Gail Douglas. You last logged in on 04/02/2009.

Instructions
If needed you may change the study/site or request access to a new study with a different role.

Info
Study: (99075) A Preliminary Study Utilizing a Flexible Endoscope for Pelvic Culdoscopy
Start Date: 03/02/2009
End Date: N/A
PI: Alexander F. Burnett, MD
Protocol Verification/IRB Approval Date: 01/30/2009
Collect Subject Date of Birth? Yes
Number of Subjects Enrolled: 2

OpenClinica: Managing Clinical Research Studies

As a Data Manager for the current site: (99075) A Preliminary Study Utilizing a Flexible Endoscope for Pelvic Culdoscopy and Protocol ID: **99075**, you may access the following modules and perform available actions authorized for your role in the study.

Actions Available

- Submit Data**
 - View All Subjects
 - Add Subject
 - Add New Study Event
 - View Study Events
 - Notes & Discrepancies
 - Import Data
- Extract Data**
 - View Dataset
 - Extract Datasets
- Manage Study**
 - Manage Users
 - Manage Subjects
 - Manage Sites
 - Manage Event Definitions
 - Manage CRFs
 - View Study Events
 - Notes & Discrepancies
 - Manage Groups
 - Manage Rules
- Business Admin**
 - Administer Users
 - Administer Subjects
 - Administer Studies
 - Administer CRFs

My OpenClinica
[Update Profile](#) [Change Study/Site](#) [Log Out](#)

Translational Components

- caBIG® caTissue Suite
- caBIG® caArray
- LimeSurvey

Biospecimen Implementation -caTissue Suite

caBIG
cancer Biomedical Informatics Grid

WINTHROP P. ROCKEFELLER
CANCER INSTITUTE
UNIVERSITY OF ARIZONA FOR MEDICAL SCIENCES

caTissue
Suite

[HOME](#) | [ADMINISTRATIVE DATA](#) | [BIOSPECIMEN DATA](#) | [SEARCH](#) | [SUMMARY](#) | [HELP](#)
Sign Out

caTissue Suite

USER PROFILE
Edit Change Password

PRIVILEGES
Admin

QUICK LINKS

WEB HOME

INCB HOME

SITE HOME

Welcome to caTissue Suite v 1.0. RC3

Dear Admin, Admin
Welcome to caTissue Suite v 1.0. RC3

Certified Browsers

- Internet Explorer 6.0
- Mozilla Firefox 2.0.0.3
- Mac Safari 2.0.3

Optimal Resolutions

- Windows - 1024 * 768
- Mac - 1024*768

Core Experimental AE Clinical AE

caTissue caTIES

[CONTACT US](#) | [PRIVACY NOTICE](#) | [DISCLAIMER](#) | [ACCESSIBILITY](#) | [REPORT PROBLEMS](#)

caTIES

- We have
 - Written an application that reformats our HL7 messages to be compatible with the caTIES
 - run 2,000 path reports
- We are currently
 - Implemented a workflow that inserts de-identified path reports from caTIES to caTissue

Tissue Procurement Facility



Tissue Procurement Facility

- Quotes:
 - The “Help” tab has been great! It is user friendly and they assist us quickly if needed
 - caTIES pulls the pathology report and de-identifies it instantaneously
 - caTissue had problems initially attaching case with multiple organ specimens but IT was able to correct this.

caBIG® caArray

- Using File System for storing an experiment and array design files rather than database (Due to cost of storage)
- Developed an auto import (Upload) all the Terabytes of experiment files and store the meta data into database for later retrieval
- Eliminating the browser dependency in file uploading
- Eliminating the burden of individually uploading of files

Techniques for Progress

- Must keep the goal in mind
 - Must understand long term pay off
- Good communication
 - Face to face, frequent meetings
 - Access to the development team: “Help”
- Rewards for extra effort
 - Carefully designed incentives

Specific Research Initiatives

- Psychiatric Research Institute
 - 2 pilot studies
- C3PR (modified)
- OpenClinica
- Spit For the Cure®
 - LimeSurvey
 - caTissue

Specific Research Initiatives

- Myeloma Institute for Research and Treatment
 - caTissue
 - caArray
 - Stand alone client of uploading from Affimetrix
 - Developing:
 - caAERS with CTCAE version 4
 - proCTCAE for patient reporting

Initiatives

- National Children's Study
 - C3PR
 - OpenClinica
 - PSC
 - caTissue
 - LimeSurvey

Initiatives

- Expand to offer participation
 - Private practice partners
 - Community research partners
 - AHECS

People Who Did The Work

- Cancer Institute
 - Peter Emanuel, M.D.
 - Thomas Kieber-Emmons, Ph.D
 - Shirley Gray, M.S.
 - CCTO: Sandy Annis, Adam Hicks
- Research Support Center
 - Tom Wells, M.D., Julia Washam, R.N.
- Bioinformatics
 - William Hogan, M.D.

People Who Did The Work

- IT Development Team
 - Cheryl Lane
 - Umit Topaloglu, Ph.D.
 - Deniz Yayla, M.S.
 - Zhidan Feng
 - Rinku Saha, M.S.
 - Matt Baker
 - Jiang Bian, M.S.
 - Sree Konduri
 - Dan Sobkaviak

Healing Garden

